Regulatory correspondence log

Project: ME-609 Country: USA IND 58,500

Date	Serial #	То	Description
1998-11-18	N/A	DAVDP	Pre-IND submission notification
1998-11-24	N/A	DAVDP	Pre-IND documentation submission
1999-04-15	N/A	Medivir	FDA comments to pre-IND documentation
1999-06-18	000	DAVDP	Initial IND application and response to pre-IND comments
1999-07-09	N/A	Inveresk (US agent)	FDA acknowledgement of IND, assignment of IND # 58,500
1999-07-21	N/A	Inveresk	FDA fax. Clearance to proceed with clinical trial 98-609-003. Comments to inital IND application (clinical and CMC).
1999-08-06	001	DAVDP	Information amendment: Chemistry. Certificates of analysis for clinical supply batches.
1999-08-24	N/A	Inveresk	FDA letter. Same content as 21 July fax.
1999-09-17	N/A	Inveresk	FDA fax. Comments on Laser Doppler Velocimetry.
1999-11-16	002	DAVDP	Response to FDA request for information, addressing comments of July 21, Aug 24, Sep 17, 1999.
2000-04-06	003	DAVDP	Information amendment: Chemistry. Stability data for clinical supply batches
2000-04-29	004	DAVDP	Protocol amendment for clinical trial 98-609-003. Amendment 2 (dated April 13, 2000) to increase patient population.
2000-07-11	005	DAVDP	Information amendment: Chemistry. Modification in manufacturing process. Certificates of analysis for new clinical supply batches.
2000-07-13	006	DAVDP	Protocol amendment for clinical trial 98-609-003. Amendment 2 (revised June 22, 2000) to increase patient population.
2000-09-18	007	DAVDP	Response to FDA request for information. Additional responses to comments of July 21, Aug 24, Sep 17, 1999.
2000-09-20	008	DAVDP	Annual report. July 21, 1999 to July 20, 2000.
2001-08-17	009	DAVDP	General correspondence: Omnicare Clinical Research is new US agent
2001-08-21	009	DAVDP	Transfer of obligation. Letter from Omnicare.
2001-09-07	010	DAVDP	Information amendment, CMC. Hydrocortisone source both France and Kalamazoo
2001-09-12	011	*DAVDP	Annual Report. July 21, 2000 to July 20, 2001
2002-09-16	012	DAVDP	Annual Report. July 21, 2001 to July 20, 2002
2003-09-04	013	DAVDP	Annual Report. July 21, 2002 to July 20, 2003
2004-02-13	014	DAVDP	Mary Holland is new US agent (fax + letter)
2004-02-16	015	DAVDP	Request for EOP2 meeting
2004-02-25	-	DAVDP	Phone call about current FDA project manager.

Date	Serial #	To	Description
2004-02-25	-	Medivir	Email. Address for desk copies.
2004-02-27	-	Medivir	Email. Questions about study reports to be submitted
2004-02-27	-	DAVDP	Email response to above questions.
2004-03-04	-	DAVDP	Phone call. Tentative information on EOP2 meeting date.
2004-03-05	016	DAVDP	Submission of non-clinical and clinical reports.
2004-03-08	-	Medivir	Phone call about status of report submission and
			request for fax with synopses and table of contents of clinical reports.
2004-03-08	100	DAVDP	Email about arrival of report submission.
2004-03-09	-	Medivir	Phone call. Confirmation on EOP2 meeting April 21
2004-03-09	-	Medivir	Written confirmation of EOP2 meeting on April 21.
2004-03-18	017	DAVDP	Briefing package for EOP2 meeting
2004-03-18	-	DAVDP	Seven desk copies of above package
2004-03-22	-	Medivir	Email confirming receipt of package and requesting electronic version of section 1.3
2004-03-25	-	DAVDP	Email submission of electronic version of section 1.3
2004-04-16	-	DAVDP	Email. Information about coming CMC updates and
2004-04-16	-	Medivir	brief CMC section overview.
2004-04-16	- -	Medivir	Email confirmation of receipt of CMC email.
2004-04-20	_	Medivir	Fax regarding April 21 meeting. Reclassification of meeting and main issues for discussion.
2004-04-30	-	DAVDP	Email submission of Medivir's meeting minutes
2004-05-17	-	Medivir	FDA record of April 21 meeting
2004-05-19	-	Medivir	Microbiology comments.
2004-09-08	018	DAVDP	Clinical development information package:
			Discussion of comparator arms
2004-09-18	019	DAVDP	Annual Report. July 21, 2003 to July 20, 2004.
2004-11-03		Medivir	Clinical comments to Sept 8 submission
2004-11-19	-	Medivir	Email response regarding internal discussions on jurisdiction of IND
2004-11-29	020	DAVDP	Request for telecon to discuss jurisdiction of IND
2004-12-08	-	DAVDP	Email correction of serial number for Nov 29 submission
2004-12-09	-	DAVDP	Email: Confirmation of information regarding
			decision that DAVDP will continue as lead division
2004-12-13	-	DAVDP	Email: Objectives for Dec 15 telecon
2004-12-15	-	-	Medivir internal meeting minutes from Dec 15 telecon
2005-01-28	021	DAVDP	Clinical development information package
			Request for telecon on clinical development plan
2005-02-11	-	Medivir	Scheduling of telecon for March 21
2005-02-18	-	DAVDP	Extra copies of clin dev information package
2005-03-11	-	J. Jenkins,	Request for designation of the lead review division
		Office of	_
		New Drugs	
2005-03-18	-	Medivir	Clinical comments to SN 021, for March 23 meeting
2005-03-28	-	Medivir	Clinical comments (one single study)

Date	Serial a	# To	Description
2005-04-04	-	DAVDP	Email with questions on content of March 28 memo
2005-04-08	-	DAVDP	Medivir summary of March 23 meeting
2005-04-15	023*	DAVDP	Major CMC amendment
*Serial #022	was inaa	lvertently not i	used
2005-04-20	-	Medivir	FDA Record of March 23 meeting
2005-04-27	p	Medivir	Clinical statistical comments referring to April 26 telecon
2005-04-29	024	DAVDP	Medivir summary of April 26 telecon and response to FDA comments of April 27
2005-05-04	025	DAVDP	Request for End of Phase 2 Meeting
2005-05-04	026	DAVDP	Proposal for acyclovir susceptibility testing and safety study in immunocompromised
2005-05-10	-	Medivir	Clinical/statistical comments to Medivir April 29 submission (#024)
2005-05-13	027	DAVDP	Medivir summary of May 11 telecon
2005-05-18	-	Medivir	Confirmation of EOP2 meeting on July 6
2005-05-19	028	DAVDP	Phase 3 study synopsis and sample size calculations
2005-05-19	029	DAVDP	Supplementary reports (stability, in vitro release and mouse efficacy) that should have been in the April 15 submission (#023)
2005-06-02	-	Medivir	Chemistry comments to Medivir April 15 submission (#023)
2005-06-03	030	DAVDP	Clinical study report for dermal irritation study
2005-06-03	031	DAVDP	Briefing package for EOP2 meeting July 6
2005-06-03	-	DAVDP	Desk copies for submissions #026, 028, 030 and 031
2005-06-30	-	Medivir	Draft comments for July 6, 2005 meeting
2005-07-01	-	DAVDP	Email clarification on formulation and dermal safety
2005-07-01		Medivir	Comment on dermal irritation study
2005-07-08	-	Medivir	Comment on photosafety study requirements
2005-07-14	032	DAVDP	Medivir minutes from July 6 EOP2 meeting
2005-08-08	-	Medivir	Official minutes from July 6 EOP2 meeting
2005-09-15	033	DAVDP	Annual report for July 21, 2004 to July 20, 2005
2005-10-01	034	DAVDP	Response to comments regarding photosafety testing and dermal irritation study
2005-10-28	035	DAVDP	Draft Patient Diary Card (for pivotal phase 3 study) submitted for comments
2005-11-09	-	Medivir	DDDP comments on photosafety response (SN#034)
2005-12-05	036	DAVDP	Response to chemistry comments June 2, 2005
2005-12-22	037	DAVDP	Request for Special Protocol Assessment for clinical protocol 609-04
2006-01-13	038	DAVDP	Clinical protocol 609-06 (immunocompromised subjects) for comments
2006-01-13	039	DAVDP	Request for wider pH limits in drug product specification
2006-01-13	040	DAVDP	Final study report for dermal sensitization study (study no 604603)

Date	Serial #	To	Description
2006-01-13	-	Medivir	Acknowledgement of receipt of Special Protocol Assessement (SN#037, submitted Dec 22, 2005, received Dec 29, 2005
2006-01-26	-	Medivir	Chemistry comments to response submitted Dec 5, 2005 (SN#036)
2006-02-10	-	Medivir	Special Procotol Assessment - comments
2006-02-27	041	DAVDP	Pediatric Use Study (request for waiver for study in younger children) and request for Type A meeting
2006-03-02	-	Medivir	Chemistry comments to SN#037 – approval of wider pH limits
2006-03-07	-	Medivir	Clinical comments to SN#038 – study in immunocompromised subjects
2006-03-14	-	Medivir	Microbiology comments to SN#038 – study in immunocompromised subjects
2006-03-15	-	Medivir	Clinical comments to SN#040 (dermal sensitization study report) – comments on clinical development from DDDP
2006-03-16	-	Medivir	Schedule of telecon on May 11, 2006 to discuss request for waiver from pediatric studies in younger children (SN#041)
2006-03-17	042	DAVDP	Response to comments on protocol 609-04 (SPA) dated Feb 10, 2006.
2006-03-29	043	DAVDP	CMC information (acyclovir cream, vehicle cream, viscosity validation, stability protocol)
2006-04-06	044	DAVDP	Response to DDDP's clinical comments dated March 15, 2006
2006-04-06	045	DAVDP	Response to clinical and microbiology comments to protocol 609-06 (IC) dated March 7 and March 14, 2006.
2006-04-18	-	Medivir	Email response regarding patient diary card submitted October 28, 2005
2006-04-28	ent .	Medivir	Statistics comments to SN#042 - plan for reassessment of sample size
2006-05-05	046	DAVDP	Final protocol study 609-04 + transfer of obligations + updated IB
2006-05-09	-	Medivir	Clinical comments to SN#041 – pediatric studies
2006-05-16	-	Medivir	FDA minutes from May 11 telecon re pediatric studies
2006-05-17	-	Medivir	Microbiological comments to SN#045 – IC study 609-06
2006-05-19	047	DAVDP	Minutes from May 11 telecon and synopsis for study 609-07 (adolescent study)
2006-06-01	048	DAVDP	Revised plan for reassessment of sample size and minutes from May 2 telecon
2006-06-29	049	DAVDP	Response to clinical comments dated Nov 9, 2005 regarding photosafety studies
2006-06-29	050	DAVDP	Response to microbiology comments dated May 17, 2006 regarding clinical protocol 609-06 (IC)

Date	Serial #	To	Description
2006-06-29	051	DAVDP	Protocol amendment no. 1 + new investigator
			Study 609-04
2006-07-21	052	DAVDP	New investigators Study 609-04
2006-08-08	-	Medivir	DDDP clinical comments to SN#049 – photosafety
2006-08-18	053	DAVDP	Protocol amendment no. 2 + new investigators
2006 00 25		Madiain	Study 609-04
2006-08-25	-	Medivir	Clinical comments to SN#048 - reassessment of
			sample size in study 609-04. Microbiology comments to SN#050 - PCR testing in study 609-06.
2006-09-18	054	DAVDP	Annual report 7/21/2005 – 7/20/2006
2006-09-18	055	DAVDP	New investigators Study 609-04
2006-09-18	056	DAVDP	Response to clinical comments dated August 8, 2006
			- commitment to perform photosafety studies
2006-09-20	-	Medivir	Emailing request for track-changes version of
			protocol in submission #053
2006-09-29	057	DAVDP	Response to microbiology comments dated August
			25, 2006 – PCR testing in study 609-06
2006-09-29	058	DAVDP	Response to clinical comments dated August 25,
			2006 – reassessment of sample size in study 609-04
2006-09-29	059	DAVDP	Resubmission of Study 609-04 Protocol Amendment
			#2: Change in Protocol
2006-10-25	060	DAVDP	New Investigators for Study 609-04
2006-12-04	061	DAVDP	New Investigators for Study 609-04
2006-12-26	062	DAVDP	New Investigators for Study 609-04
2007-02-13	063	DAVDP	Clinical protocols KGL#6201 (phototoxicity) and
			KGL#6202 (photocontact allergenicity) for
			comments
2007-02-23	064	DAVDP	Response to Microbiology Comments related to
2005 02 00		1	Protocol 609-06 (IC)
2007-03-09		Medivir	Clinical comments from DDDP to SN#63
2007.02.12	0.65	DAMDD	(phototoxicity and photocontact allergenicity)
2007-03-12	065	DAVDP	SAP for Study 609-04
2007-03-14	066	DAVDP	Final Clinical protocols KGL#6201 (phototoxicity)
			and KGL#6202 (photocontact allergenicity) + investigator information
2007-04-04		Medivir	Response to SN#064 on d-thymidine proposal
2007-04-14	067	DAVDP	Response to Microbiology Comments related to
2007-04-14	007	DAVDI	Protocol 609-06 (IC) on d-thymidine proposal
2007-04-23	068	DAVDP	Protocol Amendment No. 3. Study 609-04
2007-05-01	000	Medivir	Statistical comments to SN#065 on SAP
2007-06-12	069	DAVDP	Protocol Amendment No. 4. Study 609-04
2007-06-12	070	DAVDP	Revised SAP (Version 3.1) for study 609-04 and
	*		response to FDA comments from May 1
2007-06-21		Medivir	Response to SN#064 on d-thymidine proposal
2007-07-24		Medivir	Statistical comments to SN#070 on revised SAP
2007-08-01	071	DAVDP	New Investigators for Study 609-04
2007-08-08	072	DAVDP	New Investigator for Study 609-04

Serial #	To	Description
073	DAVDP	Pre-NDA Meeting Request
		General/Nonclinical/Clinical
074	DAVDP	Pre-NDA Meeting Request
		CMC
-	Medivir	CMC meeting granted by FDA
075	DAVDP	Annual Report for period 21/7-2006 to 20/7-2007
-	Medivir	General/nonclinical/clinical meeting granted by FDA
076	DAVDP	Study KGL6020 – Protocol Amendment 1:
		Challenge phase with individual ingredients
077	DAVDP	Protocol Amendment No. 5. Study 609-04
078	DAVDP	CMC Pre-NDA Meeting Package
079	DAVDP	General/Nonclinical/Clinical Pre-NDA Meeting
		Package
080	DAVDP	New Investigator Study 609-04
	Medivir	FDA comments on SN#079 Pre-NDA meeting
		package
	Medivir	FDA comments on SN#078 CMC Pre-NDA meeting
		package
		FDA comments on SN#076 Study KGL6202
081	DAVDP	Response to Clinical Comments - Clinical Study
		Protocol KGL #6202, Amendment 1
		FDA official minutes from CMC Pre-NDA meeting
		Response to statistical comments. SAP version 3.2
083		CMC pre-NDA Meeting – Sponsor meeting minutes
	Medivir	ROC with FDA office of Generics re. Inactive
		Ingredients Limits (Poloxamer 188; Isopropyl
004	BILLIDS	Myristate)
084	DAVDP	CMC: in vitro release data and homogeneity data for
005	DAVIDD	evaluation
085	DAVDP	Pre-NDA Meeting Request
006	DAVDD	General/Nonclinical/Clinical
080		Pre-NDA Meeting Briefing Package
	Medivir	General/nonclinical/clinical meeting granted by FDA
	Modivin	on May 22 FDA clinical comments to SN#085, request for
	Medivii	further information
087	DAVDP	Response to FDA clinical comments from May 5
007		FDA contact re Pre-NDA meeting (e-mail)
		FDA Pre-NDA meeting (c-man)
088		Response to FDA Request: Correction to pre-NDA
000	BITTE	Meeting Briefing Package
089	DAVDP	Response to FDA request for Information on study
		sites on study 609-04
090	DAVDP/	Teleconference request and briefing package (Citric
		acid content)
091		Sponsor Pre-NDA meeting minutes
	Medivir	FDA response to SN#084, homogeneity data
		FDA official Meeting minutes Pre-NDA meeting
	073 074 - 075 - 076 077 078 079 080 081 082 083 084 085 086	073 DAVDP 074 DAVDP - Medivir 075 DAVDP - Medivir 076 DAVDP 077 DAVDP 078 DAVDP 079 DAVDP Medivir Medivir 081 DAVDP Medivir Medivir 082 DAVDP Medivir Medivir 084 DAVDP 085 DAVDP 086 DAVDP Medivir Medivir 087 DAVDP 088 DAVDP 089 DAVDP 090 DAVDP 091 DAVDP

Date	Serial #	To	Description
2008-06-25	092	DAVDP	Response to FDA comments
2008-06-30		Medivir	FDA response to SN#90, cancellation of teleconference
2008-07-11	093	DAVDP	Request for clarification/Revision to FDA issued pre- NDA Meeting Minutes
2008-07-11		FDA	Request for Small Business Waiver of the New Drug Application Fee
2008-07-30	094	DAVDP	Request for Review of Sample SAS Transport File Format
2008-08-11	095	DAVDP	CMC information amendment: Appearance Specification and Microscopic Method
2008-08-28		Medivir	SAS file comments
2008-09-16	096	DAVDP	Annual Report July 2007-July 2008

NDA Regulatory correspondence log

Project: ME-609 Country: USA NDA 22-436

Date	Serial #	To	Description
2008-09-29	0000	DAVDP	505(b)2 NDA submission
2008-10-27	mail	DAVDP	Clarification of location of clinical data
2008-10-28	0001	DAVDP	Request for Trade name review
2008-10-30	0002	DAVDP	Addendum study 609-06: 12 month follow-up data
2008-11-07	mail	Medivir	Request from Division of Scientific Investigations (DSI)
2008-11-14		DSI	Study 609-04: Site specific information
2008-11-19	0003	DAVDP	Updated User Fee Cover Sheet
2008-12-05	0004	DAVDP	Updated form FDA 356h
2008-12-15		DSI	Site specific CRFs for 609-04
2008-12-23	0005	DAVDP	Response to filing communication
2009-01-08	Fax	Medivir	ROC 07: Letter re. Small Business waiver
2009-03-19	Fax	Medivir	ROC 08: Clinical comments re inspection of site 17
2009-03-19	Fax	Medivir	ROC 09: Clinical Pharmacology Comments
2009-04-03	Fax	Medivir	ROC 10: Submit draft ped. Study synopsis.
			Comments on studies 604598 and 604603
2009-04-16	0006	DAVDP	Response to clinical comments and comments from DDDP
2009-04- 17	Mail	Medivir	ROC 11: regarding submission 0006 (mail)
2009-04-17	0007	DAVDP	Response to clinical site investigation comments (March 19)
2009-04-20	0008	DAVDP	Paediatric plan
2009-04-21		Medivir	ROC 12: FDA wants more specific date for Paed study
2009-04-23		Medivir	ROC13: Statistics comments on ME-609-06
2009-04-23	0009	DAVDP	Updated paediatric study plan
2009-04-30	0010	DAVDP	Response to Clinical Pharmacology Questions (March 19)
2009-05-04		Medivir	ROC 14: Proposed tradename unacceptable
2009-05-07	Fax	Medivir	ROC 15: Annual user fees (no fees are due)
2009-05-08	0011	DAVDP	Response to Statistics Comments (April 23)
2009-06-03	0012	DAVDP	Final Clinical Study Report 609-06
2009-06-03		Medivir	ROC 16: trade name review
2009-06-10		Medivir	ROC 17: Label and Tube Example
2009-06-16		Medivir	ROC 18: Clarification from David Araojo
2009-06-24		Medivir	ROC 19: Additional Label revisions from DDDP
2009-06-29	0013	DAVDP	Response to labeling Comments/Revisions
2009-07-02		Medivir	ROC 20: Label comments microbiology
2009-07-02		Medivir	ROC 21: Attachment
2009-07-15	0014	DAVDP	Response to Labeling Comments (Microbiology – 02 July 2009)
2009-07-20		Medivir	ROC 23: CMC Comments

Serial #	То	Description
	Medivir	ROC 24: Chemistry comments
	Medivir	ROC 25: Label revision
0015	DAVDP	Response to Information request letter (20 July 2009) and Request for Labeling Revisions (27 July 2009)
	Medivir	FDA APPROVAL LETTER
		Medivir Medivir 0015 DAVDP